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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/719,916	11/21/2003	Paul Edward Kearney	33766-2037	7002

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EXAMINER	
LIN, JERRY	

ART UNIT	PAPER NUMBER
1631	

MAIL DATE	DELIVERY MODE
10/31/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/719,916	KEARNEY ET AL.	
	Examiner	Art Unit	
	Jerry Lin	1631	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *22 August 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-8,11,13-20,23,25-32,35,37-44,47,49-56,59 and 61-110* is/are pending in the application.

4a) Of the above claim(s) *1-8, 13-20, 25-32, 37-44, 49-56, 63, 65, 67, 69, 73, 75, 77, 79, 83, 85, 87, 89, 93, 95, 97, 98, 103, 105, 107, and 108* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *See Continuation Sheet* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims rejected are 11,23,35,47,59,61,62,64,66,68,70-72,74,76,78,80-82,84,86,88,90-92,94,96,99-102,104,106,109 and 110.

DETAILED ACTION

Supplemental Election/Restrictions

1. Applicant's election with traverse of Species A and Subspecies D in the reply filed on August 22, 2007 is acknowledged. The traversal is on the ground(s) that the inventions are not so distinct. This is not found persuasive because the degree of distinctness is not relevant to restriction. The inventions are distinct, and thus restriction is proper. Furthermore, because the species and subspecies have different limitations, the species and subspecies require a different field of search (for example, searching different classes/subclasses or electronic resources, or employing different search queries).

The requirement is still deemed proper and is therefore made FINAL.

2. Applicants' arguments, filed April 6, 2007, have been fully considered and they are persuasive. However, in light of the newly submitted claims and amendments, the following rejections are newly applied. They constitute the complete set presently being applied to the instant application.

Status of the Claims

Claims 11, 23, 35, 47, 59, 61, 62, 64, 66, 68, 70, 71, 72, 74, 76, 78, 80-82, 84, 86, 88, 90-92, 94, 96, 99-102, 104, 106, 109, and 110 are under examination.

Claims 9, 10, 12, 21, 22, 24, 33, 34, 36, 45, 46, 48, 57, 58, and 60 are cancelled.

Claims 1-8, 13-20, 25-32, 37-44, 49-56, 63, 65, 67, 69, 73, 75, 77, 79, 83, 85, 87, 89, 93, 95, 97, 98, 103, 105, 107, and 108 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected group, species or subspecies, there being no allowable generic or linking claim. Applicant timely traversed the species (election) requirement in the reply filed on 8/22/2007.

Claim Rejections - 35 USC § 112, 1st Paragraph

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

4. Claims 11, 23, 35, 47, 59, 61, 62, 64, 66, 68, 70, 71, 72, 74, 76, 78, 80-82, 84, 86, 88, 90-92, 94, 96, 99-102, 104, 106, 109, and 110 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter, which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

Factors to be considered in determining whether a disclosure would require undue experimentation have been summarized in Ex parte Forman, 230 USPQ 546 (BPAI 1986) and reiterated by the Court of Appeals in In re Wands, 8 USPQ2d 1400 at 1404 (CAFC 1988). The factors to be considered in determining whether undue experimentation is required include: (1) the quantity of experimentation necessary – a great deal of experimentation would be required to determine how to transform the

peptide maps based on retention time or what is a transformed retention time tolerance (2) the amount of direction presented – the specification does mention that an algorithm is used to transform the peptide maps on pages 27-30, however, it does not teach the equations or methods used to perform the transformation or a transformed retention time tolerance (3) the presence or absence of working examples – there are no working examples (4) the nature of the invention – the invention appears to require computational methods to transform a peptide map (5) the state of the prior art – the prior art does not appear to teach transforming peptide maps using retention times or using a transformed retention time tolerance (6) the relative skill of those in the art – the skill is high (7) the predictability or unpredictability of the art – the biological sciences are considered an unpredictable art and (8) the breadth of the claims – the claims include the step of deriving a retention time transformation function and using a transformed retention time tolerance.

The instant claims include a step of deriving a retention time transformation function. According the Merriam Webster online dictionary, the relevant definitions of function is "a mathematical correspondence that assigns exactly one element of one set to each element of the same or another set" (for example, f(x) = y) or "a variable (as a quality trait, or measurement) that depends on and varies with another" or "a computer subroutine; *specifically*: one that performs a calculation with variable provided by a program and supplies the program with a single result". Although the specification does mention performing a transformation of the peptide map based on the retention time at pages 27-30, the specification does not teach how one of skill in the art is to derive a

retention time transformation function. The specification does not include any mathematical equations, or teach how the retention time would modify the peptide maps, or teach any computer subroutines. Furthermore, a search of the prior art of peptide mapping utilizing LC/MS methods has not revealed a well-known method of deriving a retention time transformation function. (See, for example, Miliotis et al. "Protein Identification Platform Utilizing Micro-Dispensing Technology Interfaced to Matrix-Assisted Laser Desorption Ionization Time-of-Flight Mass Spectrometry," (2000) Volume 886, pages 99-110.) Given that the specification does not provide examples or guidance on how to derive a retention time transformation function, one of skill in the art would have to perform undue experimentation in order to determine the retention time transformation function needed to align different peptide maps.

In addition the instant claims also recite that the aligned peptide maps are with a m/z and a transformed retention time tolerance. However, the specification does not define the term "a transformed retention time tolerance", nor has a search of the prior art revealed any commonly accepted definition of the term. (See, for example, Miliotis et al. "Protein Identification Platform Utilizing Micro-Dispensing Technology Interfaced to Matrix-Assisted Laser Desorption Ionization Time-of-Flight Mass Spectrometry," (2000) Volume 886, pages 99-110.) Given that the specification does not provide examples or guidance on how to derive or how to determine a transformed retention time tolerance, one of skill in the art would have to perform undue experimentation in order to derive or determine a transformed retention time tolerance.

This rejection is necessitated by amendment.

Claim Rejections - 35 USC § 112, 2nd Paragraph

5. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

6. Claims 11, 23, 35, 47, 59, 61, 62, 64, 66, 68, 70, 71, 72, 74, 76, 78, 80-82, 84, 86, 88, 90-92, 94, 96, 99-102, 104, 106, 109, and 110 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claims 61, 71, 81, 91, and 101 each recite obtaining ion intensity data. However, this data is never used in the claims. It is unclear as to what role ion intensity data fulfills in the instant claims.

Claims 61, 71, 81, 91, and 101 each recite "transformed retention time tolerance" in step e). However, it is unclear what this phrase means. The specification does not define the term, and a search of the prior art has not revealed a commonly accepted definition.

Claims 102, 104, 106, 109, and 110 recite the limitation "the computer-readable memory". There is insufficient antecedent basis for this limitation in the claim. This term does not appear previously in the instant claims or in independent claim 101 from which they depend.

This rejection is necessitated by amendment.

Claim Rejections - 35 USC § 101

7. 35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

8. Claims 11, 23, 35, 47, 61, 62, 64, 66, 68, 70, 71, 72, 74, 76, 78, 80-82, 84, 86, 88, 90, 101, 102, 104, 106, 109, and 110 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter.

The instant claims are drawn to a process involving the judicial exception of a computational algorithm. Claims drawn to a judicial exception is non-statutory unless the claims include a practical application of that judicial exception as evidenced by a physical transformation of the claimed invention, or if the claimed invention produces a useful, tangible and concrete final result. In the instant claims, there is no physical transformation by the claimed invention, thus the Examiner must determine if the instant claims produce a useful, tangible, and concrete final result.

In determining if the instant claims have a useful, tangible, and concrete final result, the Examiner must determine each standard individually. For a claim to be "useful," the claim must produce a final result that is specific, substantial, and credible. For a claim to be "tangible," the claim must set forth a practical application of the invention that produces a real-world final result. For a claim to be "concrete," the process must have a final result that can be substantially repeatable or the process must substantially produce the same result again. Furthermore, the claim must recite a useful, tangible, and concrete final result in the claim itself, and the claim must be limited only to statutory embodiments. Thus, if the claim is broader than the statutory embodiments of the claim, the Examiner must reject the claim as non-statutory.

The instant claims do not produce a useful, concrete, and tangible final result. A useful, concrete, and tangible final result requires that the claim must set forth a practical application of the mathematical algorithm to produce a real-world result. The instant claims are drawn to a method of matching biomolecules via peptide maps. However, the last step of the claims includes matching step, which indicates there is an ongoing process. This final step does not indicate that a result has necessarily been produced. Thus the instant claims do not require that a result must be produced. Since there is no final result in the claims, the instant claims do not include a useful, concrete, and tangible final result. This rejection could be overcome by amendment of the claims to recite that a result of the method is outputted a user or display or outputted in a user readable format.

In addition, claims 101, 102, 104, 106, 109, and 110 are drawn to a computer usable media, which may be drawn to carrier waves. However, carrier waves are non-statutory *per se*. Thus, claims 101, 102, 104, 106, 109, and 110 are non-statutory.

This rejection is necessitated by amendment.

Withdrawn Rejections

9. Applicant's arguments and amendments, see Remarks, filed 4/6/2007, with respect to the rejection(s) of claim(s) 9-12, 21-36, 45-48, 57-60 under 35 U.S.C. §§112, 101, and 102 as being anticipated by Gorenstein (US 5,969,228) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn.

However, upon further consideration, a new ground(s) of rejection is made in view of the newly submitted claims and amendments.

Conclusion

No claim is allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Contact Information

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jerry Lin whose telephone number is (571) 272-2561. The examiner can normally be reached on 10:00-6:30, M-F.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Majorie A. Moran can be reached at (571) 272-0720. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/JL/

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